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September 29, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Division of Management Systems & Policy
Office of Human Resources & Management Services

Re: Docket No. 00D-1455

To Whom it May Concern:

The FDA needs to more completely address the following issues in the draft guidance document "Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief."

In the attachment to Section 1, under the number of output channels, there is a statement "Method of Channel Isolation?" The Agency needs to clarify what it wants to see in this answer—output transistors, capacitors? Furthermore, this information is not really important or relevant to the safety of the product and could be deleted.

The measurement of maximum output voltage and current is requested in a range of 300 to 2000 ohms. The Agency should specify three specific values of impedance for measurement so this information may easily be compared from device to device. We would recommend 500, 800, and 1200 ohms. Readings at higher or lower impedance ranges are not applicable to current stimulator applications, and since most devices are voltage controlled, they would not yield any useful or additional information regarding the safety or efficacy of these devices.

An entry should be included in the pulse generator output specifications to indicate whether the device is voltaged controlled or current controlled.

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Under Multiphasic Waveforms—the phase duration needs to be defined. A drawing of a stimulation pulse width with defined parameters would be most helpful in this regard.

The net charge that is to be measured and which should be listed as part of the pulse generator output specifications—is that estimated or measured? If it is measured, information regarding the setup and measurement method should be included so that this specification has some meaning.

The maximum current density is listed as "mA/cm^2." It would be more accurate to request ""mA/cm^2/phase" so the current density per pulse is listed. I believe this is the measurement the Agency would like.

The same for a maximum power density, it should be listed per phase.

Under Section 2, "Lead(s) Electrodes and Programmer Descriptions," it asks for the impedance of the lead. Does the Agency actually want the resistance from terminal end to electrode contact? If not, the exact method of measurement should be defined.

Information regarding the battery of the implant is listed in Section 2. This should be listed in Section 1 under Pulse Generator Specifications. This should include usable battery amp-hour capacity and estimated implant life.

In device testing under Electrical Characteristics, the loads to be tested are 300 to 2000 ohms. As mentioned previously, this range should be reduced to better match the values which can be expected in actual use.

Sincerely,

Bill Borkan
BB:jak

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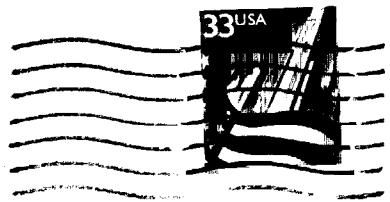

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